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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
JONES, DAMERON LEVEST	

ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/622,160	SPINDLER ET AL.	
	Examiner	Art Unit	
	D. L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *2/20/07; 3/6/06; & 12/8/05*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-57* is/are pending in the application.

4a) Of the above claim(s) *1-47 and 57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *48-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/6/06 & 12/8/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

APPLICANT'S INVENTION

1. Applicant's invention is directed to various methods of evaluating caloric restriction and methods of identifying caloric restriction mimetics as set forth in independent claims 1, 15, 30, 32, 37, 48, and 57.

Note: Claims 1-57 are pending.

APPLICANT'S ELECTION

2. The Examiner acknowledges receipt of Applicant's election of Group VI (claims 48-56) with traverse on 2/20/07. The traversal is on the grounds that it is not an undue burden to search the full scope of the instant invention. Applicant's arguments are not persuasive because the groups of inventions are distinct because they involve method steps that are non-obvious over one another and are directed to methods of evaluating/identifying distinct methods. Thus, the restriction is deemed proper and is made FINAL.

WITHDRAWN CLAIMS

3. Claims 1-47 and 57 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

DOUBLE PATENTING REJECTIONS

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 48-56 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 5, 10-12, 19, 20, and 25 of U.S. Patent No. 6,406,853. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a

method of identifying an intervention wherein a biological sample is utilized, various biochemical measurements are obtained, and caloric restriction occurs. The claims differ in that the patented invention is limited to identifying an intervention that mimics the effects of caloric restriction in cells whereas the instant invention is not limited to any specific type of caloric intake. However, the skilled practitioner in the art would recognize that the instant invention encompasses the patented invention.

112 SECOND PARAGRAPH REJECTIONS

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 48-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 48-56: The claims as written are ambiguous because it is unclear what type of intervention is being is being claimed. Specifically, in independent claim 48, is one identifying an intervention for narcotics withdrawn, overeating, obesity, weight loss, etc. The claim as written just states that it is directed to a method of identifying an intervention, but never discloses why or what the intervention is a result of. In addition, it is unclear what 'at least biological measurement' Applicant is analyzing to determine if the intervention 'mimics at least some effects of caloric restriction'. Also, it is unclear what effects are being examined to determine if they mimic caloric restriction. Since,

claims 49-56 depend upon independent claim 48 that is found to be ambiguous, those claims are also ambiguous for the same reasons.

Claim 50, lines 2-3: The claim is ambiguous because of the phrase 'substantially normal amount of calories'. In particular, it is unclear what group the phrase 'substantially normal amount of calories' is directed to. In other words, the phrase is relative to the group referred to as normal. For example, is the group that Applicant is referring to a group of teens, senior citizens, athletes, obese subjects, rats, premature babies, etc. because what one group considers as a 'normal' amount of calories may be too many or too little for another group.

Claim 51: The claim as written is ambiguous because there are an unlimited number of possible genes present in a subject. Thus, it is unclear what expresses Applicant is comparing since the expressions are sometimes dependent upon the subject's age, disease/condition, etc.

Claim 52: The claim as written is ambiguous because it is unclear what Applicant is claiming as a long term calorie dietary program. In particular, it is unclear what time frame the program is directed to. For example, depending upon the type of intervention being sought one would determine if the program were 1 year, 3 months, 4 years, etc. In other words, a skilled practitioner in the art would not be ale to determine what time period Applicant is claiming that the dietary program should be restricted.

Claim 53: The claim as written is ambiguous because it is unclear what Applicant is claiming as a short term calorie dietary program. In particular, it is unclear what time frame the program is directed to. For example, depending upon the type of

intervention being sought would determine if the program is 1 day, 3 days, 4 weeks, etc. In other words, a skilled practitioner in the art would not be ale to determine what time period Applicant is claiming that the dietary program should be restricted.

103 REJECTIONS

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blundell et al (CNS Drugs, 1998, Vol. 6, pages 473-495).

Blundell et al disclose a study involving serotonin and appetite regulation in the pharmacological treatment of obesity. Blundell et al disclose that evidence has outlined the effects of diet composition on energy balance and bodyweight gain. As a result of such interest in the effect of serotonergic drugs on preference for high fat diets and diets characterized by energy dense foods coupled with potent palatability and carbohydrate craving (see entire document, especially, 'Summary', pages 473-474), various studies were conducted to analyze subjects administered various treatments. One study of Blundell et al involved the cafeteria diet model wherein the animal selects between a supplemented, or cafeteria, diet (standard laboratory food with extra macronutrient) and a standard food control. Dietary induced obesity in the rat is a means of assessing the effect of the macronutrient supplement on the subject. Rats treated long term with

dexfenfluramine and exposed to a cafeteria diet with a fat supplement did not display dietary induced obesity, unlike control animals that were treated with a placebo (page 482, columns 1-2, bridging paragraph). In a second experiment to induce bodyweight gain, subjects were administered hyperfat diets and compared with the results of a low fat diet. The dexfenfluramine was found to be effective for long periods of time with very high fat diets (page 482, second paragraph, first complete paragraph). Also, Blundell et al disclose that many studies have demonstrated a short term inhibition of hunger, both before and after a meal, in both lean and obese individual when dexfenfluramine is administered acutely (page 483, first column, second complete paragraph). In addition, Blundell et al disclose that with extended administration (over several weeks) to obese women, dexfenfluramine reduced hunger at specific points during the diurnal cycle (before and after a midday meal, before the evening meal, and before going to bed) and also reduced the perceived frequency and strength of urges to eat (page 483, first column, third complete paragraph). In a 2-week study of fluoxetine, hunger was significantly reduced before and after the midday meal when food intake was also measured. Also, the administration of sibutramine for 14 days resulted in a significant reduction in hunger (page 483, first column, last complete paragraph). Table I (page 484) disclose a summary of studies that have investigated the effects of serotonergic drugs on food intake in humans. In Figure 4 (page 485), the effect of dexfenfluramine or placebo on bodyweight following weight reduction in obese patients who were placed on a very low calorie diet for 8 weeks is disclosed. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to generate

a method of identifying an invention as set forth in independent claim 48 because Blundell et al disclose a method of identifying an intervention in obese individuals wherein a subject is exposed to a drug/placebo and at least one biochemical measurement is taken after expositing the subject to the drug. The experimental design of Blundell et al is designed to mimic some of the effects of caloric restriction. After the subjects are administered the drug, the drug is eventually withdrawn and data taken to see how the subject responses in the absence of the drug. Thus, both Applicant and Blundell et al disclose overlapping inventions.

SPECIFICATION

10. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

In particular, Applicant's attention is directed to page 29, lines 6 and 7. However, Applicant is respectfully requested to review the entire disclosure and remove all references to websites from the specification.

COMMENTS/NOTES

11. The full scope of Group VI was searched.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

D. L. Jones
Primary Examiner
Art Unit 1618

June 8, 2007